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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,168	07/31/2003	Bradley Kropp	85820.639	7538

30589 7590 11/30/2004

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EXAMINER

ALONZO, NORMA LYN

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,168	KROPP ET AL.	
	Examiner	Art Unit	
	Norma C Alonzo	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 6-7, 10, 13, 15-16, 24-27, 44-47, drawn to a urinary tract tissue graft composition comprising embryonic stem cells and a segment of small intestinal submucosa, wherein said stem cell is seeded on the surface of the segment of a small intestinal submucosa, a method for making said graft and a method for using said graft, classified in class 435, subclass 1.1.
- II. Claims 1-3, 6-7, 10, 13, 15-16, 24-27, 44-47, drawn to a urinary tract tissue graft composition comprising adult stem cells and a segment of small intestinal submucosa, wherein said stem cell is seeded on the surface of the segment of small intestinal submucosa, a method for making said graft and a method for using said graft, classified in class 435, subclass 1.1.
- V. Claims 4-5, 8-9, 11-12, 14, 17-23, 28-43, 48-55, drawn to a urinary tract tissue graft composition comprising embryonic stem cells, a segment of small intestinal submucosa, and further comprising one cell type, wherein said cell type or said stem cell is seeded on the surface of the small

intestinal submucosa, a method for making said graft and a method for using said graft, classified in class 435, subclass 1.1.

- VI. Claims 4-5, 8-9, 11-12, 14, 17-23, 28-43, 48-55, drawn to a urinary tract tissue graft composition comprising ~~at~~ adult stem cells, a segment of small intestinal submucosa, and further comprising one cell type, wherein said cell type or said stem cell is seeded on the surface of the small intestinal submucosa, a method for making said graft and a method for using said graft, classified in class 435, subclass 1.1.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of Groups I and II are patentably distinct from the inventions of Groups III and IV. Whereas the inventions are related as being drawn to urinary tract tissue grafts, methods for making said grafts, and methods for using said grafts, the inventions comprise compositions that have different physical structures, functions, and utilities. For example, the urinary tract tissue grafts of groups I and II comprise at least one type of stem cell and a segment of small intestinal submucosa having a mucosal and serosal surface. In contrast, the urinary tract tissue grafts of groups III and IV comprise at least one type of stem cell, a segment of small intestinal submucosa, and further comprising at least one type of cell, wherein said cell is selected from the group consisting of smooth muscle cells and urothelial cells. The grafts of groups I and II comprising only a stem cell and small intestinal submucosa has a different physical

structure, function and utility from the grafts of Groups III and IV which comprise a stem cell, a small intestinal submucosa, and a smooth muscle or urothelial cell. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

3. The inventions of Groups I and III are patentably distinct from the inventions of Groups II and IV. Whereas the inventions are related as being drawn to urinary tract tissue grafts, methods for making said grafts, and methods for making said grafts, the inventions comprise compositions that have different physical structures, functions and utilities. For example, the embryonic stem cell of Groups I and III have a different physical structure, function, and utility from the adult stem cells of Groups II and IV. An embryonic stem cell can only be derived from the inner cell mass of the blastocyst and is pluripotent, whereas an adult stem cell can be derived from adult animals and can only differentiate into a limited number of cell types, multipotent. Additionally, while transgenic animals are predictably produced using embryonic stem cells, the production of transgenic animals using adult stem cells is unpredictable. Further, search for embryonic stem cells in the art would not encompass adult stem cells. The art of embryonic stem cells has therefore acquired a separate status in the art from adult stem cells and examination of an invention comprising embryonic stem cells would require a different field of search from an invention comprising adult stem cells. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

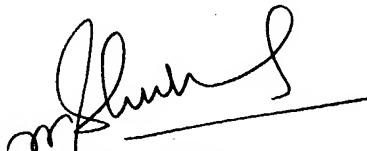
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Norma C Alonzo whose telephone number is 571-272-2910. The examiner can normally be reached on 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1632

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NCA



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER